

**REMARKS**

Entry of the foregoing, re-examination and reconsideration of the subject matter identified in caption, as amended, pursuant to and consistent with 37 C.F.R. §1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, claim 1 has been amended to more clearly distinguish the invention from the cited art. Support for the amendment to claim 1 may be found, for example, on page 4, lines 5-6 of the specification. Claims 1-10 remain pending in this application.

Claims 1-3, 5, 6 and 8-10 were rejected under 35 U.S.C. §102(b) as anticipated by WO 97/32644 for the reasons provided on page 2 of the Office Action. In addition, claims 1, 2, 4-6 and 8-10 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,872,259 to Reuter for reasons set forth on page 3 of the Office Action.

Reconsideration of these rejections is respectfully requested in view of the amendment to claim 1 and for at least the following reasons.

WO '644 and Reuter '259 both relate to processes for separating a desired substance from an aggregate mixture in which a three phase dispersion is formed, the first phase comprising the aggregate mixture, the second phase comprising a liquid transport phase, and the third phase comprising a surface upon which the desired substance can crystallize. Both references fail to anticipate (or render obvious) Applicant's claimed invention at least for the reason that each and every feature of the claims is not disclosed or

suggested. For reasons more fully explained below, the processes referred to in these documents are not the same as and do not render the present claims obvious.

At the outset, it is noted that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628,631,2 USPQ2d 1051,1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226,1236, 9 USPQ2d 1913,1920 (Fed. Cir. 1989). In the present case, WO '644 and Reuter '259 fail to teach or suggest step (e), i.e., dissolving additional impure substance in the emulsion-filtrate whereby the level of impurities builds up in the emulsion. As such, the presently claimed process is not anticipated by the processes disclosed in the cited documents.

With reference to WO '644, Applicant notes that the only additional substance added is of the type that is crystallized out. The impurities that do not crystallize in the emulsion crystallization process remain in constant concentration and are in equilibrium with the aggregate feed mixture (e.g., in column (3) according to Fig. 1). Only a flow of the desired substance to be crystallized out takes place, while the impurities, once equilibrium is established, remain in the crude mixture. In contrast, Applicant's claimed process provides for the crystallization of desired compounds and for adding the aggregate mixture (i.e., both the impurities and the desired substance to be crystallized) directly into the emulsion from which crystallization takes place.

The continuous crystallization process described in WO '644 (which requires the apparatus of Fig. 1) is designed in a complex way with an external column (3), filters (8) and (10) and heat exchangers (9,9a). The purpose of this complex design is to selectively dissolve and extract, at elevated temperature, only the desired material provided in crude form in column (3). No undissolved matter enters vessel (4) due to filtration of solids with filter (10). Therefore, only those components of the crude which can be dissolved by an undersaturated emulsion will be introduced into vessel (4) and then be depleted there by crystallization. After recycling through (9), the circulating emulsion is already saturated to equilibrium at the extraction/reloading temperature with the undesired impurities which do not crystallize out, so that no further net amounts of such impurities can be dissolved. These impurities do not crystallize out in the emulsion (4) in Fig. 1 of WO '644. The desired substance that is crystallized out in pure form in (4) can be replaced with new desired compound (e.g., enantiomer, isomer or the like) by passing the emulsion through the heat exchanger and then through column (3).

The net effect of the process of WO '644 is that the same amount of impurities is always present in dissolved form in the system (i.e., no net extraction of the impurities is obtained), while only the desired substance is crystallized out in (4) and replaced with redissolved substance in column (3). A net enrichment of desired substance and net removal of desired substance out of the system in pure form results. Although not all crude material is dissolved during the extraction process, the undissolved by-products and impurities (the waste material) are carried away through exit (15), either continuously or

stepwise (i.e., batchwise). See, e.g., page 17, lines 16-17 of WO '644. Thus, the net amount of impurities in dissolved form always remains constant. No out-crystallization of these impurities takes place. Instead, a net mass transport of the desired compound that is allowed to crystallize takes place from the crude to the emulsion, and from the emulsion to the crystal surface.

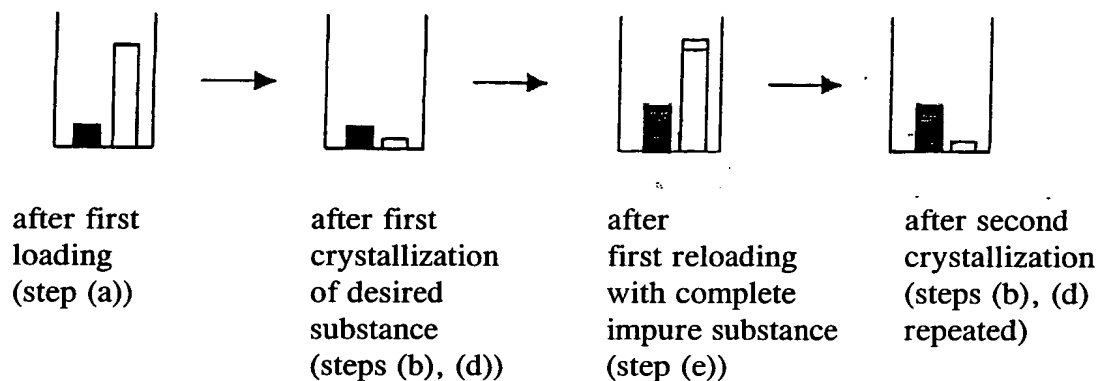
As mentioned in Applicant's specification at page 1 (especially lines 27-34), continuous operation of the process of WO '644 can lead to a number of cumbersome, even highly undesirable deficiencies. For example, the equipment required is complicated, the external column and filters are susceptible to clogging, and a risk of loss of emulsion during removal of the crude material exists, to name a few. Additional difficulties with normal emulsion crystallization may also be present; for example, obtainable yields may be substantially lower than with classical (solution) crystallization due mainly to the difficulty in removing solvent from the mother liquor (which may, e.g., lead to breakdown of the emulsion), and that surfactants usually cannot be distilled away in parallel to solvents. Some emulsions also cannot be loaded with impure substance in high concentrations since this would lead to emulsion instability, unworkable viscosity and/or suboptimal crystal growth (see, e.g., page 1, line 36 to page 2, line 3 of Applicant's specification). Applicant's process, however, overcomes these disadvantages in part since additional impure substance is now dissolved directly in the emulsion filtrate, leading to improved yield and lowered costs, as well as avoiding the difficulties of operating a process according to WO '644.

The foregoing arguments are equally applicable against Reuter '259. Reuter '259 also describes a process for separating a desired substance from an aggregate mixture in which a three phase dispersion is formed; however, there is no disclosure or suggestion of dissolving additional impure substance in the emulsion filtrate according to step (e) of claim 1. While Reuter '259 makes use of microemulsions rather than macroemulsions according to WO '644, the same reasoning applicable against WO '644 clearly establishes that Applicant's claims are not anticipated by Reuter '259.

It appears to be the Examiner's position that since the crystals obtained by the processes of the references are not 100% pure, some impurities might be present in the emulsion when it is reintroduced to the aggregate mixture. Respectfully, Applicant disagrees and provides the following description in support of his position.

By the present amendment, claim 1 now specifies that the level of impurities, due to replenishment with impure substance (=substance to be isolated and impurities) builds up in step (e) over that of the original emulsion used in step (a) (or further recycled emulsion after further repetition). This distinction can be exemplified by the following drawing where black bars represent impurities and clear bars represent the substance to be purified that is mostly crystallized out:

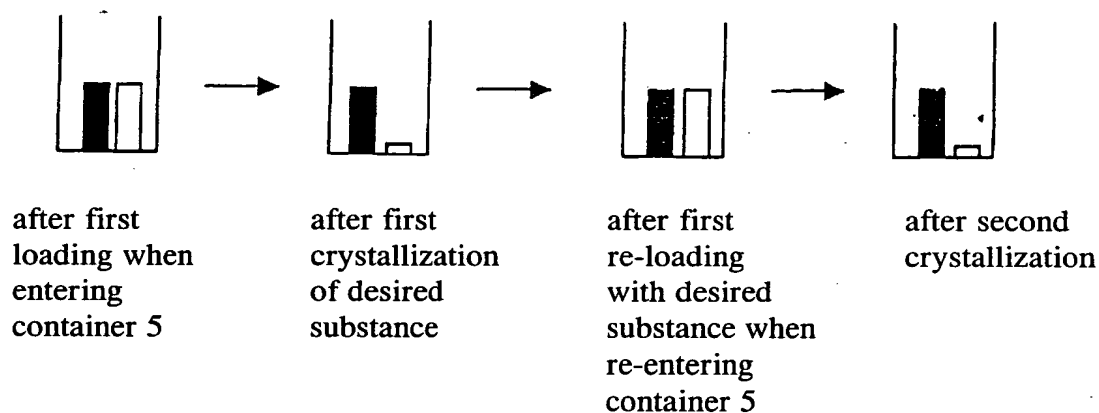
Scheme I: Present Invention



Thus, it can be observed that the concentration of impurities increases with each step.

In contrast, in the cited art, the concentration of impurities, due to the steady state, remains constant after each cycle, as illustrated in Scheme II:

Scheme II: Prior Art



Here, the concentration of impurities remains constant after each cycle (no growth of the black bar). In other words, there is no build up in the continuous crystallization process described in the references.

The process as explicitly disclosed in the cited references are steady state operations as opposed to the claimed method which is an unsteady state operation. Further, step (e) in the present claims specifies dissolving additional impure substance in the emulsion-filtrate whereby the level of impurities builds up in the emulsion. In the references, additional impure substance is not dissolved but only molecules of impurities which are substituted by other molecules of impurities.

For at least the foregoing reasons, Applicant respectfully submits that the present claims are novel and patentable over WO '644 and Reuter '259. Withdrawal of the §102 rejections is requested.

Claim 7 stands rejected under 35 U.S.C. §103(a) as unpatentable over WO '644 as applied above and further in view of U.S. Patent No. 3,141,743 to Marsh as set forth on page 3 of the Office Action. In addition, claim 7 was rejected under 35 U.S.C. §103(a) as unpatentable over Reuter '259 as applied above and further in view of Marsh '743 for reasons given on page 4 of the Office Action. Reconsideration of these rejections is requested for at least the reasons which follow.

Initially, Applicant submits that claim 7 is patentable over Reuter '259 or WO '644 combined with Marsh '743 for the reasons discussed above in connection with the §102(b) rejections.

Marsh '743 relates to a crystallization process for the recovery of various sulfate salts of aluminum. Washing of the obtained crystals is mentioned (column 5, line 28 et seq), which may be conducted during centrifugation. However, Marsh '743 fails to remedy the deficiencies noted above for WO '644 and Reuter '259. In particular, Marsh '743 provides nothing to teach or suggest step (e) according to claim 1, i.e., dissolving additional impure substance in the emulsion-filtrate whereby the level of impurities builds up in the emulsion. Instead, Marsh '743 only provides information that centrifugation and washing of crystals is known for crystal separation. As such, the present claims are not *prima facie* obvious over the proposed combination of Reuter '259 or WO '644 with Marsh '743.

In view thereof, the §103(a) rejections of claim 7 should be reconsidered and withdrawn. Such action is respectfully requested.

Claims 1-10 were rejected under 35 U.S.C. §103(a) as unpatentable over the newly cited article by Davey et al. entitled "Purification of molecular mixtures below the eutectic by emulsion crystallization," 22 June 1995, Nature, vol. 375, pages 664-666 in view of U.S. Patent No. 4,010,142 to Hurlock et al. The Examiner's rationale is set forth on pages 4-5 of the Office Action. Reconsideration and withdrawal of this rejection are respectfully requested for at least the following reasons.

The Davey et al. article does not mention or suggest any recycling technique at all. While dealing with a specific emulsion crystallization, the article provides no indication that emulsion recycling is considered possible or suggested. Nothing is disclosed therein



that might suggest recycling of the emulsion filtrate as described in step (e) of claim 1 of the present invention.

Turning to the secondary reference, Hurlock et al. '142 teaches a very specific process for the purification of acrylamide from water, involving vacuum stripping of a dilute solution of aqueous acrylate, effecting crystallization by cooling, centrifuging, washing with water and recycling the mother liquor and rinse liquor to produce again a dilute solution of acrylamide. Thus, Hurlock et al. '142 does not recognize or suggest the technical solution of how to achieve a simple, generally applicable emulsion crystallization process in a highly economical way and how to perform emulsion crystallization in high yield without using a very complicated apparatus such as that in Fig. 1 of WO '644. The Hurlock et al. '142 process initially produces a dilute solution, which is then vacuum-stripped at a temperature of 25 to 50°C, to produce an acrylamide concentration of 80%. Thus, in fact, most of the mother liquor is removed. Such a procedure would be impossible to be imposed on most emulsions as it would lead to their break-down.

Further, in the process of Hurlock et al. '142, the removed solvent is then discarded. Nothing is said or suggested to remove other compounds during this distillation process. It is safe to predict that almost all organic compounds present in the dilute acrylamide-water solution will be removed during the vacuum stripping process at least to some degree. Note also that such waster stripping basically corresponds to a steam distillation process. This reference then teaches to replenish the mother liquor with fresh water that before has been used to wash the crystal cake. Nothing is disclosed in Hurlock

et al. '142 as to how this complicated and highly specific process for acrylamide crystallization might be transformed into emulsion crystallization.

Thus, the process of Hurlock et al. '142 differs from the present invention in all key elements and surely cannot be considered to teach or even suggest transfer of its highly specific procedure to emulsion crystallization, especially not to the present procedure which provides a new key principle for emulsion crystallization, namely, emulsion crystallization with recycle and step-wise build-up of impurities in the emulsion after each recycle step as a way to achieve high yields in emulsion crystallization without complicated processes and devices.

For at least the reasons enumerated above, the combined disclosures of Davey et al. and Hurlock et al. '142 fail to render obvious the process described in claims 1-10. Accordingly, the §103(a) rejection based on combining the above mentioned documents should be withdrawn and such action is earnestly solicited.

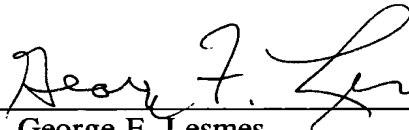
From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order and such action is earnestly solicited. If there are any questions concerning this paper or the application in general, the Examiner is invited to telephone the undersigned at (703) 838-6683 at his earliest convenience.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

Date: January 28, 2004

By: \_\_\_\_\_



George F. Lesmes

Registration No. 19,995

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620